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The efficacy of nutraceuticals in the treatment of chronic insomnia

Submission date
18/07/2024

Recruitment status
No longer recruiting

Registration date
30/07/2024

Overall study status
Completed

Last Edited
24/07/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sleep disorders and anxiety disorders, in addition to constituting a complex syndrome, represent a clinical condition in which various interconnected pathophysiological mechanisms contribute to determining the clinical phenotype.
Therefore, the ideal drug in these patients, in addition to having an anxiolytic and hypno-inducing action, should have a modulatory action on chronic stress, mood, inflammatory state, with a therapeutic action also on the cognitive and physical dimensions of the clinical syndrome.
A natural supplement dedicated to a population of patients suffering from sleep disorders associated with specific and non-specific states of anxiety might be made up of 4 distinct therapeutic principles (plant extracts, amino acids, vitamins, minerals) with a strengthening action on the physiological mechanisms responsible for regulating the sleep-wake rhythm and the homeostasis of the neurotransmitter and immune systems involved in the regulation of the state of alertness, mood and the hypothalamic-pituitary-adrenal axis.
The therapeutic rationale is based on the principle of the synergy of action exerted by constituents, such as plant extracts, capable of exerting a direct action on the GABA-A receptors implicated in the induction of sleep and on the mechanisms of chronic inflammation; the precursor amino acids for the synthesis of substances such as GABA, melatonin, dopamine and serotonin; vitamins, enzymatic catalysts for the synthesis of molecules involved in the regulation of the circadian rhythm and mood states; minerals, essential as cofactors for the correct functioning of neurotransmitters, neuro-hormones, and the chemical reactions connected to them. The main objective of this prospective, observational, open-label study, lasting eight weeks, was to evaluate the efficacy and safety of a phytotherapeutic and nutraceutical compound in a sample of patients suffering from insomnia disorder associated with states of anxiety.

Who can participate?
Patients suffering from insomnia disorder according to the DSM-V criteria, associated with a state of anxiety measured according to STAI-Y1/Y2.

What does the study involve?
All participants received the same sachet of powdered herbal mixture, vitamins, essential amino acids and trace elements to be taken one per day one hour before falling asleep

What are the possible benefits and risks of participating?
The pharmacological properties of the compound under study and the related benefits, would be to reduce the state of hypervigilance and consequently, improve the quantity and quality of sleep. No concerns about the safety profile of the study compound, were anticipated

Where is the study run from?
Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
April 2018 to October 2022

Who is funding the study?
Ecupharma S.r.l. (Italy)

Who is the main contact?
Dr Gianluca Bruti, gianluca.bruti@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Gianluca Bruti

Contact details
Antonio Bertoloni avenue, 26 C
Rome
Italy
00197
+39-06-4997661
dip.odonto@cert.uniroma1.it

Additional identifiers

Protocol serial number
0000698

Study information

Scientific Title
A combination of herbs, vitamins, trace elements and essential amino acids in the treatment of patients with insomnia disorder associated with anxiety symptoms: an observational, pilot, open-label, prospective, eight-week study

Study objectives
To evaluate the efficacy and safety of a nutraceutical compound composed of a combination of herbs, vitamins, trace elements and essential amino acids in the treatment of patients with chronic insomnia associated with anxiety.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This study was performed in a private office and did not require any institutional regulation.

Primary study design
Observational

Study design
Observational prospective open-label

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of patients suffering from chronic insomnia and anxiety states.

Interventions
The study was conducted on a clinical sample of 28 patients suffering from insomnia disorder according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), associated with a state of anxiety. The sample study was clinically evaluated at baseline (T0), and after four (T1) and eight weeks (T2) of phytotherapeutic and nutraceutical treatment. There was no further systematic follow-up after the eight-week study

Intervention Type
Other

Primary outcome(s)
Measured at baseline and week four:
1. The Pittsburgh Sleep Quality Index (PSQI)
2. STAI-Y1 (anxiety)

Key secondary outcome(s)
1. PSQI at baseline and eight weeks
2. STAI-Y2 at baseline and eight weeks
3. Beck Depression Inventory (BDI) at four and eight weeks
4. Fatigue Severity Scale (FSS) at four and eight weeks
5. Depression and Anxiety Scale Short form – 21 (DASS-21) at four and eight weeks
6. Patient global impression of improvement - severity (PGI-S) at four and eight weeks
7. Rapid Stress Assessment (RSA) at four and eight weeks
8. Insomnia Severity Index at four and eight weeks
9. General health (SF-36) at four and eight weeks

Completion date
25/10/2022

Eligibility

Key inclusion criteria

Patients suffering from chronic insomnia according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders and the third edition of the International Classification of Sleep Disorders (DSM-V), associated with a state of anxiety.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Major depressive disorders
2. Substance abuse disorders
3. Pregnancy
4. Unstable clinical status

Date of first enrolment
23/09/2021

Date of final enrolment
20/09/2022

Locations

Countries of recruitment
Italy

Study participating centre
EurekAcademy
Antonio Bertoloni, 26 C
Rome
Italy
00197

Sponsor information

Organisation
Sapienza University of Rome

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
Industry

Funder Name
Ecupharma S.r.l.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
Gianluca Bruti; gianluca.bruti@gmail.com

IPD sharing plan summary
Available on request